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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/513,362

02/25/2000

Mark S Chee

A-67851-2/DJB/RMS/DCF

7034

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08/13/2004

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EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

94

Advisory Action

Application No.

09/513,362

Applicant(s)

CHEE ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1637

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 22 July 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-34.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

JEFFREY FREDMAN
PRIMARY EXAMINER

8/11/04

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments were not considered persuasive. A) Regarding the rejection of claims 1-4, 6-10, 12-17 and 22-27 under 35 U.S.C. 103(a) over Navot et al. and Walt et al., Applicants argue that Navot et al. do not teach large scale sequence determination involving a plurality of target nucleic acids, and that there is no motivation to combine Navot et al. and Walt et al. Further, Applicants argue that "Establishing that the prior art would have suggested the claimed method requires an underlying factual showing of a suggestion, teaching, or motivation to combine the prior art references and is an "essential evidentiary component of an obviousness holding." Brown & Williamson Tobacco, 229 F.3d at 1124-25 (quoting C.R. Bard, Inc. v. 513 Sys., Inc., 157 F.3d 1340, 1351-52 (Fed.Cir.1998)); see also C.R. Bard at 1351 (obviousness requires some suggestion, motivation, or teaching in the prior art where to select the components that the inventor selected and use them to make the new device; In re Kotzab, 217 F.3d 1365, 1370 (Fed. Cir. 2000) (there must be some motivation, suggestion or teaching in the prior art of the desirability of making the specific combination that was made by the applicant). The evidentiary showing must be clear and particular and broad conclusory statements about the teachings of the cited references, standing alone, are not "evidence." Brown & Williamson Tobacco, 229 F.3d at 1125 (quoting In re Dembiczak, 175 F.3d 994, 1000 (Fed.Cir.1999), abrogated on other grounds by In re Gartside, 203 F.3d 1305, 53 USPQ2d 1769 (Fed.Cir.2000)).

However, as noted in the previous office actions, there is a perfectly valid motivation to combine the two references. In this case, Navot et al. teach pyrosequencing of nucleic acids which may be attached to microbeads in an electrophoresis-free system, and attachment to the solid support provides confinement to the sample (col. 15, lines 1-14), and Walt et al. teach microbeads with attached nucleic acids, distributed randomly on the surface of the fiber optic bundle, creating an microbead array (col. 3, lines 35-45; col. 4, lines 35-38; col. 8, lines 15-19; col. 9, lines 41-67; col. 10, lines 1-47). Both references teach microbeads, and Walt et al. teaches an efficient and inexpensive way of creating an array (col. 4, lines 53-58). Therefore, provided with the teachings of Navot et al. and Walt et al., a skilled artisan would be motivated to use the microbead array of Walt et al. to detect the microbead sequencing reactions of Navot et al. Further, the paragraph from Walt et al. cited by Applicants (col. 4, lines 44-59) provides additional support for the motivation to use the references, since Walt et al. teach synthesis of bioactive agents, which is what DNA sequencing is. As can be seen from the previous office actions and responses to arguments provided, the statements about motivation are supported by clear factual showing of the motivation present in both references, and are not simply broad, conclusory statement.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicants further bring on the argument about the lack of factual support for the motivation, which was addressed above. The rejection is maintained.

B) Regarding the rejection of claims 5 and 11 (claim 33 was also included in this rejection, but Applicants do not mention it) under 35 U.S.C. 103(a) over Navot et al. and Walt et al., further in view of Balch et al., Applicants argue that there was no motivation to combine Navot et al. and Walt et al. This argument was addressed above.

The rejection is maintained.

C) Regarding the rejection of claims 18-21 and 28-30 under 35 U.S.C. 103(a) over Navot et al. and Walt et al., further in view of Nyren et al., Applicants argue that there is no motivation to combine the kit components of two different references. As stated in the previous office actions, the kits were conventional in the field of molecular biology at the time of the invention and provided convenience and cost-effectiveness for practitioners in the art. Further, both Navot et al. and Nyren et al. teach pyrosequencing and pyrosequencing kits, with Navot et al. teaching a kit comprising primers and DNA polymerase (col. 6, lines 63-67; col. 7, lines 1-10; col. 9, lines 5-7), and Nyren et al. teach a kit comprising a sequencing primer, a polymerase, a detection enzyme means for identifying pyrophosphate release, dNTPs or ddNTPs (page 20, second paragraph; page 21, first paragraph). Therefore, as can be seen from these two references, there is a strong motivation to combine different reaction components into kits. Since strong motivation exists to combine Walt et al. with Navot et al., it would have been obvious to add components of the array of Walt et al. to the kit (see also MPEP 2144).

2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103

RATIONALE MAY BE IN A REFERENCE, OR REASONED FROM COMMON KNOWLEDGE IN THE ART, SCIENTIFIC PRINCIPLES, ART RECOGNIZED EQUIVALENTS, OR LEGAL PRECEDENT

The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art established scientific principles, or legal precedent established by prior case law. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); In re Eli Lilly & Co., 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); In re Nilssen, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); Ex parte Clapp, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection); and Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning).

The rejection is maintained.